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Registration Decision RD2013-23

Soybean Oil

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Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6604-E2
Ottawa, Ontario K1A 0K9

Internet: pmra.publications@hc-sc.gc.ca
healthcanada.gc.ca/pmra
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra.infoserv@hc-sc.gc.ca

Canada

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Registration Decision for Soybean Oil

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of Scotts Soybean Oil Technical, Scotts Ecosense Indoor Insect Killer Aerosol and Scotts Ecosense Indoor Insect Killer Ready-To-Use, containing the technical grade active ingredient soybean oil, to kill ants, cockroaches, house crickets, earwigs, silverfish, carpet beetles and spiders on contact inside the home.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the consultation document[1] Proposed Registration Decision PRD2013-05, *Soybean Oil*. This Registration Decision[2] describes this stage of the PMRA's regulatory process for Soybean Oil and summarizes the Agency's decision and the reasons for it. The PMRA received no comments on PRD2013-05. This decision is consistent with the proposed registration decision stated in PRD2013-05.

For more details on the information presented in this Registration Decision, please refer to PRD2013-05, which contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[3] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value[4] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

3 "Acceptable risks" as defined by subsection 2(2) of *Pest Control Products Act*.

4 "Value" as defined by subsection 2(1) of *Pest Control Products Act* "...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact".

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

What Is Soybean Oil?

Soybean oil is the active ingredient in the end-use products Scotts EcoSense Indoor Insect Killer Aerosol and Scotts EcoSense Indoor Insect Killer Ready-To-Use. These products rapidly kill ants, carpet beetles, cockroaches, crickets, earwigs, silverfish, and spiders on contact when applied directly to these pests as a crack and crevice treatment or spot spray inside the home such as along baseboards or under sinks.

Health Considerations

Can Approved Uses of Soybean Oil Affect Human Health?

Soybean Oil is unlikely to affect human health when it is used according to label directions.

Potential exposure to soybean oil may occur when handling and applying the end-use products Scotts Ecosense Indoor Insect Killer Aerosol and Scotts Ecosense Indoor Insect Killer Ready-To-Use, which are insecticides for killing ants, cockroaches, house crickets, earwigs, silverfish, carpet beetles, and spiders inside the home. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

In laboratory animals, the active ingredient, soybean oil, was of low acute toxicity via the oral, dermal, and inhalation routes of exposure. It was not a skin or eye irritant, and was not a skin sensitizer. Soybean oil is, however, a priority allergen. Consequently, 'Warning, contains the allergen soy' is required on the technical grade active ingredient and end-use product labels. Both end-use products are expected to be of low acute toxicity via the oral, dermal, and inhalation routes of exposure. Both are moderate skin irritants and minimal eye irritants, but are not dermal sensitizers. As a result of the skin irritation, the labels for these end-use products require the hazard signal words, 'WARNING SKIN IRRITANT'.

Risks in Non-Occupational / Consumer Environments

Estimated risk for non-occupational / consumer exposure is not of concern provided that directions specified on the label are observed.

Exposure to individuals coming in contact with Scotts Ecosense Indoor Insect Killer Aerosol and Scotts Ecosense Indoor Insect Killer Ready-To-Use is not expected to result in unacceptable risk when used according to the label directions.

Precautionary and hygiene statements on the label are considered sufficient to protect individuals from any unnecessary risk due to consumer exposure.

Environmental Considerations

An environmental assessment was not required for this application

Value Considerations

What Is the Value of Scotts EcoSense Indoor Insect Killer Aerosol and Scotts EcoSense Indoor Insect Killer Ready-To-Use?

Scotts EcoSense Indoor Insect Killer Aerosol and Scotts EcoSense Indoor Insect Killer Ready-To-Use are fast acting products used to kill ants, carpet beetles, cockroaches, crickets, earwigs, silverfish and spiders when applied directly to the pest inside the home.

Scotts EcoSense Indoor Insect Killer Aerosol and Scotts EcoSense Indoor Insect Killer Ready-To-Use contain soybean oil which suffocates the target pest. Since the mode of action is by physical contact (i.e., suffocation), it is unlikely that pests will develop resistance to soybean oil. These products can be used with other pest control practices and products for the labelled pests. They also represent a new non-conventional chemistry for the domestic class market that can be used inside homes.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures on the label of Scotts Soybean Oil Technical and the associated end-use products to address the potential risks identified in this assessment are provided below.

Key Risk-Reduction Measures

Human Health

Since soybean oil is collected from soy, a priority allergen, the principal display panel for the Scotts Soybean Oil Technical and both end-use products require the signal words, "Warning, contains the allergen soy."

The signal words, 'WARNING SKIN IRRITANT' are required on the principal display panels of the labels for the two end-use products. The statements, 'Causes skin irritation. DO NOT get on skin. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.' are required for the PRECAUTIONS section of the secondary display panel for both end-use products.

Other Information

The relevant test data on which the decision is based (as referenced in PRD2013-05) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

Any person may file a notice of objection[5] regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of the Health Canada's website (Request a Reconsideration of Decision, healthcanada.gc.ca/pmra) or contact the PMRA's Pest Management Information Service.

[5] As per subsection 35(1) of the *Pest Control Products Act*.